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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/146,783	09/03/1998	NICHOLAS JOHN DEACON	9606Z-IY	9825

7590 11/02/2004
SCULLY SCOTT MURPHY AND PRESSER
400 GARDEN CITY PLAZA
GARDEN CITY, NY 11530

EXAMINER

PARKIN, JEFFREY S

ART UNIT	PAPER NUMBER
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1648

DATE MAILED: 11/02/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Interview Summary	Application No.	Applicant(s)	
	09/146,783	DEACON ET AL.	
	Examiner	Art Unit	
	Jeffrey S. Parkin, Ph.D.	1648	

All participants (applicant, applicant's representative, PTO personnel):

(1) Jeffrey S. Parkin, Ph.D.

(3) Frank S. Digiglio (Reg. No. 31,346).

(2) James Housel, SPE 1648.

(4) Xiaochun Zhu.

Date of Interview: 18 October 2004.

Type: a) ☒ Telephonic b) ☐ Video Conference
c) ☐ Personal [copy given to: 1) ☐ applicant 2) ☐ applicant's representative]

Exhibit shown or demonstration conducted: d) ☐ Yes e) ☒ No.
If Yes, brief description: _____.

Claim(s) discussed: all pending claims.

Identification of prior art discussed: prior art of record.

Agreement with respect to the claims f) ☒ was reached. g) ☒ was not reached. h) ☐ N/A.

Substance of Interview including description of the general nature of what was agreed to if an agreement was reached, or any other comments: See Continuation Sheet.

(A fuller description, if necessary, and a copy of the amendments which the examiner agreed would render the claims allowable, if available, must be attached. Also, where no copy of the amendments that would render the claims allowable is available, a summary thereof must be attached.)

THE FORMAL WRITTEN REPLY TO THE LAST OFFICE ACTION MUST INCLUDE THE SUBSTANCE OF THE INTERVIEW. (See MPEP Section 713.04). If a reply to the last Office action has already been filed, APPLICANT IS GIVEN ONE MONTH FROM THIS INTERVIEW DATE, OR THE MAILING DATE OF THIS INTERVIEW SUMMARY FORM, WHICHEVER IS LATER, TO FILE A STATEMENT OF THE SUBSTANCE OF THE INTERVIEW. See Summary of Record of Interview requirements on reverse side or on attached sheet.

Examiner Note: You must sign this form unless it is an Attachment to a signed Office action.


Examiner's signature, if required

Summary of Record of Interview Requirements

Manual of Patent Examining Procedure (MPEP), Section 713.04, Substance of Interview Must be Made of Record

A complete written statement as to the substance of any face-to-face, video conference, or telephone interview with regard to an application must be made of record in the application whether or not an agreement with the examiner was reached at the interview.

Title 37 Code of Federal Regulations (CFR) § 1.133 Interviews

Paragraph (b)

In every instance where reconsideration is requested in view of an interview with an examiner, a complete written statement of the reasons presented at the interview as warranting favorable action must be filed by the applicant. An interview does not remove the necessity for reply to Office action as specified in §§ 1.111, 1.135. (35 U.S.C. 132)

37 CFR §1.2 Business to be transacted in writing.

All business with the Patent or Trademark Office should be transacted in writing. The personal attendance of applicants or their attorneys or agents at the Patent and Trademark Office is unnecessary. The action of the Patent and Trademark Office will be based exclusively on the written record in the Office. No attention will be paid to any alleged oral promise, stipulation, or understanding in relation to which there is disagreement or doubt.

The action of the Patent and Trademark Office cannot be based exclusively on the written record in the Office if that record is itself incomplete through the failure to record the substance of interviews.

It is the responsibility of the applicant or the attorney or agent to make the substance of an interview of record in the application file, unless the examiner indicates he or she will do so. It is the examiner's responsibility to see that such a record is made and to correct material inaccuracies which bear directly on the question of patentability.

Examiners must complete an Interview Summary Form for each interview held where a matter of substance has been discussed during the interview by checking the appropriate boxes and filling in the blanks. Discussions regarding only procedural matters, directed solely to restriction requirements for which interview recordation is otherwise provided for in Section 812.01 of the Manual of Patent Examining Procedure, or pointing out typographical errors or unreadable script in Office actions or the like, are excluded from the interview recordation procedures below. Where the substance of an interview is completely recorded in an Examiners Amendment, no separate Interview Summary Record is required.

The Interview Summary Form shall be given an appropriate Paper No., placed in the right hand portion of the file, and listed on the "Contents" section of the file wrapper. In a personal interview, a duplicate of the Form is given to the applicant (or attorney or agent) at the conclusion of the interview. In the case of a telephone or video-conference interview, the copy is mailed to the applicant's correspondence address either with or prior to the next official communication. If additional correspondence from the examiner is not likely before an allowance or if other circumstances dictate, the Form should be mailed promptly after the interview rather than with the next official communication.

The Form provides for recordation of the following information:

- Application Number (Series Code and Serial Number)
- Name of applicant
- Name of examiner
- Date of interview
- Type of interview (telephonic, video-conference, or personal)
- Name of participant(s) (applicant, attorney or agent, examiner, other PTO personnel, etc.)
- An indication whether or not an exhibit was shown or a demonstration conducted
- An identification of the specific prior art discussed
- An indication whether an agreement was reached and if so, a description of the general nature of the agreement (may be by attachment of a copy of amendments or claims agreed as being allowable). Note: Agreement as to allowability is tentative and does not restrict further action by the examiner to the contrary.
- The signature of the examiner who conducted the interview (if Form is not an attachment to a signed Office action)

It is desirable that the examiner orally remind the applicant of his or her obligation to record the substance of the interview of each case. It should be noted, however, that the Interview Summary Form will not normally be considered a complete and proper recordation of the interview unless it includes, or is supplemented by the applicant or the examiner to include, all of the applicable items required below concerning the substance of the interview.

A complete and proper recordation of the substance of any interview should include at least the following applicable items:

- 1) A brief description of the nature of any exhibit shown or any demonstration conducted,
- 2) an identification of the claims discussed,
- 3) an identification of the specific prior art discussed,
- 4) an identification of the principal proposed amendments of a substantive nature discussed, unless these are already described on the Interview Summary Form completed by the Examiner,
- 5) a brief identification of the general thrust of the principal arguments presented to the examiner,
(The identification of arguments need not be lengthy or elaborate. A verbatim or highly detailed description of the arguments is not required. The identification of the arguments is sufficient if the general nature or thrust of the principal arguments made to the examiner can be understood in the context of the application file. Of course, the applicant may desire to emphasize and fully describe those arguments which he or she feels were or might be persuasive to the examiner.)
- 6) a general indication of any other pertinent matters discussed, and
- 7) if appropriate, the general results or outcome of the interview unless already described in the Interview Summary Form completed by the examiner.

Examiners are expected to carefully review the applicant's record of the substance of an interview. If the record is not complete and accurate, the examiner will give the applicant an extendable one month time period to correct the record.

Examiner to Check for Accuracy

If the claims are allowable for other reasons of record, the examiner should send a letter setting forth the examiner's version of the statement attributed to him or her. If the record is complete and accurate, the examiner should place the indication, "Interview Record OK" on the paper recording the substance of the interview along with the date and the examiner's initials.

Continuation of Substance of Interview including description of the general nature of what was agreed to if an agreement was reached, or any other comments: Applicants' representatives requested clarification concerning the basis for the enablement rejection of claims 49, 50, 66, 67, 85, 120-144, and 153-157. The basis for the rejection has been clearly set forth in prior office actions. To date, an efficacious HIV-1 or -2 vaccine does not exist. This is because of several factors including, inter alia, a lack of understanding of the correlates of protective human immunity, a lack of understanding of suitable immunogens/adjuvants that will lead to protection, the quasispecies nature of HIV infection which leads to immune escape, the lack of suitable animal models in which to assess vaccine efficacy, and the general unpredictability of the art (to date, several large-scale HIV-1 vaccine trials have been conducted and all failed to generate meaningful immune responses). Moreover, applicants are employing a replication-impaired, nef-deficient HIV-1 construct as the immunogen, which provides another set of complications as set forth in prior office actions. Applicants' representatives inquired as to what type of evidence or data might overcome the rejection (i.e., animal studies). Applicants were advised that there are currently no art-recognized animal models that would enable the skilled artisan to make direct extrapolations to the clinic. Applicants were advised that while the agency does not require clinical data, nevertheless, in a highly unpredictable art such as HIV vaccine development the only meaningful results may ultimately come from a properly designed clinical trial. Applicants' representatives suggested that in a sense, the Sydney cohort represents a clinical trial. Applicants were advised that the Sydney cohort study fails to answer some important virological and immunological questions. For instance, it is not clear if the immune response is due to a strong immunogen or if it is simply controlling an effete virus that fails to replicate efficiently. The nature and titer of the actual protective immune response still remain to be elucidated. Moreover, while several of the cohort patients remained asymptomatic for a considerable period of time, nevertheless, many of them appear to be progressing toward the disease state. The Ruprecht references relied upon in the rejection clearly identify several concerns pertaining to the utilization of replication-impaired, nef-deficient HIV-1 viruses as immunogens. Applicants' representatives also discussed the art rejection of claims 145-152 and 158 under Desrosiers. It was argued by the representatives that the reference relied upon does not teach the precise genomic deletion (e.g., 9281-9438) identified by applicants that is responsible for the less pathogenic state of these HIV-1 mutants. The representatives noted that the genomic deletion results in removal of the carboxyl terminus of Nef and disrupts a portion of the U3 coding region in the LTR. It was argued that this specific combination of mutations in both a regulatory gene and regulatory region were novel and unobvious. Applicants' arguments on the immunogenic composition claims appeared reasonable pending further review of the prior art .